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April 27, 2021

VIA ECF

The Honorable Robert B. Kugler
United States District Court Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets Room 1050
Camden, NJ 08101

Special Master the Honorable Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower
18th Floor
Philadelphia, PA 19103

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Kugler and Special Master Vanaskie:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Case Management Conference with the Court on April 28, 2021.

1. Hetero Discovery Dispute Status

A. Discovery Disputes

Defendants Hetero Drugs Ltd. and Hetero Labs Ltd. (collectively, "HLL") is continuing to work cooperatively with Plaintiffs to address Plaintiffs' concerns regarding its discovery productions. HLL has made document productions to address the specific documents Plaintiffs requested, provided a detailed report of HLL's document management systems, and is working toward resolving the discreet issues remaining.



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Since our last Case Management Conference on April 14, 2021, HLL has made two supplemental document productions to Plaintiffs and has provided its responses to Plaintiffs' inquiries regarding HLL's ESI storage and collection. On April 14, 2021, HLL produced Document Indexes, Site Master Files, and SOPs relevant to its Unit I location. Thereafter, on April 21, 2021, HLL produced Product Quality Reviews from its Unit V location as well as Corrective and Preventive Action Reports, Quality Assurance and Production Department Protocols from its Unit I location, and Product Quality Reviews. That same day, HLL provided Plaintiffs and Your Honor with a detailed account of its document management systems, which HLL volunteered to provide during the April 14, 2021 Case Management Conference. This included the questions set forth in Plaintiffs' letter dated November 11, 2019, which was served upon several other defendants in this matter, but not HLL, as well as additional subjects raised by Plaintiffs' Counsel in subsequent email correspondence with the Court. HLL is currently scheduled to meet and confer with Plaintiffs regarding any outstanding questions Plaintiffs have regarding the letter, on April 27, 2021.

On April 23, 2021, HLL received correspondence from Plaintiffs setting forth additional concerns regarding HLL's document metadata. HLL has conferred with its ESI vendor regarding these issues and is preparing to make a subsequent overlay file production to remedy this metadata concern. Plaintiffs additionally raised issues regarding documents previously deemed non-responsive, which HLL is presently investigating in order to de-designate any responsive documents and promptly produce to Plaintiffs.



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Accordingly, HLL is continuing to diligently address all issues raised by Plaintiffs with very few, narrow and resolvable issues remaining. HLL has conferred with Plaintiffs and we are intending to proceed with depositions of HLL's witnesses this week, commencing on Thursday, April 29, 2021.

B. COVID Deposition Issues

HLL further writes to advise the Court of its concerns about the completion of Manufacturer Defendant depositions due to the evolving Covid-19 situation in India. At this time, two HLL witnesses have tested positive for the virus, resulting in the postponement of their depositions. With the recent news of outbreaks coming out of India, we fear there will be even more postponements forthcoming. Accordingly, HLL brings this information to the Court's attention as it is now unlikely that all depositions can be re-scheduled and completed by June 1, 2021.

2. Aurobindo Discovery Status and Plaintiffs' Request for Sanctions

A. Aurobindo Document Production and Deposition Status

The Aurobindo parties are feverishly working to produce all responsive documents to the Plaintiffs. As of this writing, the data production for the US entities is substantially complete. Furthermore, Counsel anticipates the production of certain hand-written log books and other hand written documents referenced in Aurobindo depositions in the next few days. Similarly, over 250 attorneys are reviewing documents from the Indian entity for production as expeditiously as possible. In fact, at the time of this writing, Aurobindo's ESI vendor is currently working on a document production for the Indian entity, and it is anticipated another document production from



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the Indian entity will occur in the next few days. Counsel is optimistic to complete its production by May 3, 2021.

Aurobindo has proposed the following dates for depositions:

- Venkat Kota: May 12, 2021
- Steve Lucas: May 18, 2021 and May 19, 2021

The Aurobindo parties anticipate working with the Plaintiffs to produce all remaining agreed upon witnesses at a mutually convenient time. Similarly, the Plaintiffs left the Bhadresh Doshi, Prasad Gorijavolu, and Jasleen Gupta depositions open. Additionally, Blessy Johns still has another day of testimony. The Aurobindo parties will work with Plaintiff's counsel if the need arises to re-depose Mr. Doshi, Mr. Gorijavolu, or Ms. Gupta. Similarly, the Aurobindo parties are prepared to work with Plaintiffs' counsel to schedule Blessy Johns' second day of testimony.

B. Plaintiffs' Motion for Sanctions

Plaintiffs have filed a forty (40) page Motion for Sanctions pertaining to the Aurobindo defendants. Therein, Plaintiffs are seeking the most severe sanctions available and have requested the Court strip Aurobindo of its defenses in this matter. In light of the severity of sanctions sought, the Aurobindo parties respectfully request fourteen (14) days to file a response, making the response date May 7, 2021. Accordingly, the Aurobindo parties anticipate addressing this issue at the May 12, 2021 mid-month conference.

C. Plaintiffs' Privilege Log Inquiries

As detailed above, the Aurobindo parties have continued to make substantial productions of ESI materials. After Aurobindo's most recent discovery production, an amended privilege log was served on Plaintiffs. Plaintiffs have raised some concern over the designation of many such



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documents. The parties have agreed to meet and confer on April 27th in an effort to resolve any potential dispute. In anticipation of an amicable resolution, the Aurobindo parties are preparing an overlay document production and a corresponding amended privilege log.

3. Wholesaler Discovery Status

Wholesaler Defendants provided Plaintiffs' counsel with a red line of the draft proposed "Second Set of Requests for Production to Wholesaler Defendants" on March 23, 2021. The parties met and conferred regarding that redline version on April 13, 2021. During the meet and confer, the parties generally discussed Plaintiffs' requests that Wholesaler Defendants produce "agreements relating to [Wholesaler Defendants'] purchase" of VCDs with Manufacturer Defendants and "agreements relating to [Wholesaler Defendants'] sale of VCDs to Retail Pharmacy Defendants. Plaintiffs' counsel confirmed that Plaintiffs' previously served requests for production to Manufacturer Defendants and Retail Pharmacy Defendants included requests for those agreements, although Plaintiffs' counsel was not certain all agreements had been produced. Therefore, in the interest of eliminating duplicative discovery to Wholesaler Defendants and providing for an accounting of the agreements produced to date, counsel for Wholesaler Defendants agreed to provide Plaintiffs' counsel with a list of the Manufacturer Defendants with whom each Wholesaler has an agreement applicable to the purchase/supply of VCDs. Similarly, Plaintiffs' counsel agreed to provide Wholesaler Defendants with a list of Retail Pharmacy Defendants that have produced agreements with Wholesaler Defendants and identify which Retail Pharmacy Defendants have agreements with which Wholesaler Defendants. The parties have exchanged that information and they are in the process of determining whether the listings are



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complete – i.e. whether Plaintiffs have received production of agreement from all Manufacturer Defendants identified on Wholesaler Defendants listing and whether Retail Pharmacy Defendants have identified all Wholesaler Defendants with whom they have agreements.

Wholesaler Defendants’ proposed red line of Plaintiffs’ draft requests also included a revised request as to “SOPs sufficient to determine the general method of [Wholesaler Defendants’] VCD inventory management.” During the meet and confer, Plaintiffs’ counsel stated that Plaintiffs are seeking to understand how Wholesaler Defendants order, stock, re-order drugs, including VCDs, generally. Plaintiffs’ counsel asked counsel for Wholesaler Defendants to look into whether the proposed request, as revised by Wholesaler Defendants, would provide documents with that information. Wholesaler Defendants are in the process of investigating their SOPs and preparing a response to Plaintiffs’ counsel’s question.

Wholesaler Defendants’ proposed red line of Plaintiffs’ draft requests also included revised requests that provide for the production of all communications between Wholesaler Defendants and Manufacturer Defendants and Retail Pharmacy Defendants regarding the recalls of VCDs at issue. Plaintiffs’ counsel is considering whether the requests as revised are agreeable.

Finally, during the meet and confer the parties discussed the production of certain organizational charts with respect to Plaintiffs’ request for information regarding persons involved in purchases, sales, and the recall of VCDs. Wholesaler Defendants advised that they may not each have organizational charts, as they understand that term, applicable to those specific issues. Wholesaler Defendants are each investigating what organizational charts, if any, may be responsive, and will meet and confer further with Plaintiffs’ counsel regarding the production of



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organizational charts or potentially some alternative type of responsive document, to the extent those exist.

4. Retailer Discovery Status

On Friday, April 23, the Pharmacy Defendants filed a letter brief (ECF 1181) addressing the status of the negotiation of Plaintiffs' draft Requests for Production, including their position on why negotiation of certain draft requests should be tabled for the time being, while the pleadings are in flux. In the past week, counsel for the various Pharmacy Defendants also met individually with Plaintiffs' counsel to discuss each Pharmacy's prior production of indemnity provisions as it relates to one of the draft requests proposed by Plaintiffs. The Pharmacy Defendants also have discussed the draft 30(b)(6) topics with Plaintiffs, and anticipate sending Plaintiffs a redline of the topics this week.

5. The ZHP Parties' Request to Reschedule the Deposition of ZHP President Baohua Chen and Plaintiffs' Request for Mr. Chen's Custodial File

A. The Deposition of ZHP President Baohua Chen Should be Rescheduled.

The ZHP Parties request the Court to permit the proposed, tentative deposition dates of ZHP's President, Baohua Chen, to be rescheduled from May 30-June 1 (U.S. time) to dates during the week of June 21 or after, so that the ZHP Parties' forthcoming motion for protective order to preclude Mr. Chen's deposition can account for the deposition testimony of all of ZHP Party witnesses, including, in particular, Linda Lin, Jie Wang, and Jun Du, ZHP's Vice Chairman and the CEO of the ZHP Parties' U.S. entities, whose depositions have been noticed for May 3-6 (U.S. time), May 9-10 (U.S. time), and May 27-28 (U.S. time), respectively. As set forth below, each



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of these witnesses is likely to be questioned on topics pertinent to Plaintiffs' claimed basis for seeking Mr. Chen's deposition, and thus rescheduling Mr. Chen's deposition is necessary to evince the purpose of Magistrate Judge Schneider's order granting the ZHP Parties leave to move for a protective order to preclude Mr. Chen's deposition based on a sufficient prior record of deposition testimony. To be sure, rescheduling Mr. Chen's deposition by a matter of weeks will not prejudice Plaintiffs, and will permit this Court to consider the ZHP Parties' motion for a protective order on a sufficient record of testimony, as expressly permitted and anticipated by Magistrate Judge Schneider's prior decision.

I. Judge Schneider Granted the ZHP Parties Leave to Move for a Protective Order to Preclude Mr. Chen's Deposition Based on a Sufficient Deposition Record.

In a letter dated December 21, 2020 ([ECF 685](#)), Plaintiffs argued that 6 witnesses, including Mr. Chen, should be added to the list of ZHP Party witnesses to be scheduled for deposition. Plaintiffs identified the following areas they believe warrant Mr. Chen's deposition: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

See [ECF 685](#).

Following argument, Judge Schneider ordered that proposed, tentative deposition dates be provided for all of the ZHP Party witnesses identified in Plaintiffs' letter, but, for certain of those witnesses, including Mr. Chen, Judge Schneider granted the ZHP Parties leave to move for a protective order to preclude their depositions following the depositions of the other ZHP Party deponents. See Hrg. Tr. 1-05-21 at 26:1-5 ("If it turns out that the depositions are not ordered,



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then they can be taken off the schedule; but to make sure there's no lag or undue delay, ZHP will be ordered to give *proposed tentative dates* for these witnesses' depositions as well as Mr. Chen.") (emphasis added). Judge Schneider said the depositions of those witnesses should be "*planned*" but "*without prejudice to ZHP to present a record that, in fact, these depositions are cumulative, duplicative, not material, et cetera.*" Hrg. Tr. 12-22-20 at 42:2-9 (emphasis added). In particular, as to Mr. Chen, Judge Schneider ruled, "if other depositions are taken, you might have a better record to show, in fact, that this testimony is, in fact, duplicative, cumulative, or nonmaterial," and "*after a sufficient deposition record is developed*, ZHP is granted leave to file a Motion for Protective Order to quash Mr. Chen's deposition." Hrg. Tr. 12-22-20 at 41:7-10; [ECF 704](#).

II. The Depositions in May 2021 Necessitate Rescheduling the Proposed, Tentative Dates for Mr. Chen's Deposition.

As the President of ZHP, Mr. Chen is an apex witness. The apex doctrine applies "a rebuttable presumption that a high-level official's deposition represents a significant burden upon the deponent and that this burden is undue absent the two factors set forth in the apex doctrine, which go to the lack of a more convenient, less burdensome, and less expensive alternative." *United States ex rel. Galmines v. Novartis Pharm. Corp.*, No. CV 06-3213, 2015 WL 4973626, at *2 (E.D. Pa. Aug. 20, 2015). Courts in this Circuit evaluate two factors when assessing whether the deposition of a high-ranking executive is appropriate: (1) whether the executive or top-level employee has personal or unique knowledge on relevant subject matters; and (2) whether the information sought can be obtained from lower-level employees or through less burdensome means, such as interrogatories." *Younes v. 7-Eleven, Inc.*, No. CV 13-3500 (RMB/JS), 2015 WL



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12844446, *2 (D.N.J. Aug. 19, 2015) (citing *Ford Motor Company v. Edgewood Properties, Inc.*, C.A. No. 06-1278, 2011 WL 2517133, at *3 (D.N.J. June 23, 2011)).

There are five remaining depositions of ZHP Party witnesses scheduled to occur in May 2021. Based on Plaintiffs' assertions as to why they believe the deposition of Mr. Chen is warranted, three of those witnesses are particularly pertinent to the ZHP Parties' forthcoming protective order motion: Linda Lin, Jie Wang, and Jun Du. Given their job responsibilities, each of these witnesses will be deposed on the topics Plaintiffs have claimed warrant Mr. Chen's deposition. Their testimony, along with that of the other 14 ZHP Party deponents (which includes 8 other 30(b)(6) witnesses), obviate the purported need for Mr. Chen's deposition.

Linda Lin is currently scheduled to be deposed on May 3-6, 2021 (U.S. time). Ms. Lin is ZHP's Director of Regulatory Affairs. Ms. Lin has been designated as a 30(b)(6) witness to testify on the following topics:

- Topic 38: The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
- Topic 39: The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's finished dose.
- Topic 40: ZHP's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.
- Topic 41: ZHP's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for ZHP's Valsartan API Drug Master Filings.



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Jie Wang is currently scheduled to be deposed on May 9-10, 2021 (U.S. time). Mr. Wang is ZHP's Vice President of Marketing and Sales. Mr. Wang has been designated as a 30(b)(6) witness to testify on the following topics, among others:

- Topic 43: ZHP's oral and written communications with ZHP's valsartan API Customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan API.
- Topic 47: All credits, indemnification, refunds, and/or penalties paid or provided by or to ZHP in connection with the nitrosamine contamination of ZHP's valsartan API and ZHP's valsartan finished dose.
- Topic 50: Tracing of batches and lots of ZHP's valsartan API sold downstream and ultimately intended for use by consumers in the United States.
- Topic 52: The pricing of ZHP's valsartan API that was ultimately sold in the United States.
- Topic 53: The pricing of ZHP's valsartan finished dose that was ultimately sold in the United States.

Jun Du is currently scheduled to be deposed on May 27-28, 2021 (U.S. time). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See Exhibit A

(ZHP00076708). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



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[REDACTED]

[REDACTED]

[REDACTED]

The apex witness doctrine requires the Court to evaluate the testimony of key witnesses in order to carefully consider whether the apex factors have been satisfied. *See Reif v. CNA*, 248 F.R.D. 448, 453-54 (E.D. Pa. 2008) (“[Plaintiff] must demonstrate the insufficiency of interrogatories or the depositions of the lower level employees before obtaining a deposition of [the CEO].”). Judge Schneider recognized this principle in granting the ZHP Parties leave to move for a protective order to preclude Mr. Chen’s deposition upon a sufficiently developed record of testimony. Given their ability to cover topics on which Plaintiffs might question Mr. Chen, ZHP would be severely prejudiced, and Plaintiffs would receive unfair advantage, if ZHP was not permitted to include the testimony of Ms. Lin, Mr. Wang, and Mr. Du in their protective order motion simply due to the timing of their depositions. *See U.S. ex rel. Galmines*, 2015 WL 4973626, at *1 (“The [apex] doctrine recognizes that depositions of high-level officers severely burden those officers and the entities they represent, and that adversaries might use this severe burden to their unfair advantage.”).

Given their job responsibilities, and the 30(b)(6) topics for which they have been designated, it cannot be reasonably disputed that the depositions of Ms. Lin, Mr. Wang, and Mr. Du will cover the same topics Plaintiffs claim warrant the deposition of Mr. Chen. As the head of Regulatory Affairs, Ms. Lin has the most knowledge about ZHP’s communications with the FDA, and has been designated to cover all of the 30(b)(6) topics Plaintiffs’ have noticed in this area. Likewise, Jie Wang, as ZHP’s Vice President of Marketing and Sales, will cover the 30(b)(6)



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topics relating to the recall of ZHP's API and ZHP valsartan sales and pricing. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thus, only after Plaintiffs depose Ms. Lin, Mr. Wang, and Mr. Du will the ZHP Parties and the Court have the record necessary to evaluate whether Mr. Chen's deposition will be cumulative, duplicative, and not material. *See Reif*, 248 F.R.D. at 453-54. Indeed, courts generally require a fully developed record before determining whether to permit additional depositions. *See Alaska Elec. Pension Fund v. Pharmacia Corp.*, No. CIV.A. 03-1519 (AET), 2006 WL 6487632, at *3 (D.N.J. Aug. 22, 2006) (citing district court cases requiring "a party to fully exhaust its allotted depositions before seeking leave to take additional depositions" and denying plaintiffs' request to take fact depositions).

Accordingly, Mr. Chen's deposition should be rescheduled to the week of June 21 or after to permit the ZHP Parties to account for the testimony of these key witnesses in the motion to preclude Mr. Chen's deposition.

III. Plaintiffs Will Not Be Prejudiced by Rescheduling the Proposed, Tentative Dates for Mr. Chen's Deposition.

Plaintiffs served their notice to depose Mr. Chen on April 15, 2021. *See* [ECF 1158](#). During a meet and confer on April 23, 2021, the ZHP Parties proposed rescheduling Mr. Chen's deposition to the week of June 21 or 28, given Judge Schneider's grant of leave to the ZHP Parties to file a motion to preclude the deposition of Mr. Chen based on a sufficient record of testimony, noting



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that Mr. Chen's deposition was tentatively proposed to begin one business day after Mr. Du's deposition was scheduled to conclude on May 28. The parties then discussed a briefing schedule for ZHP Parties' motion to preclude the deposition of Mr. Chen that would allow the ZHP Parties to file their opening brief the week of June 1, after Mr. Du's deposition. In an email sent after close of business that day, Plaintiffs rejected the ZHP Parties' proposal to reschedule the deposition of Mr. Chen, without asserting any basis for their refusal. *See Exhibit B.*

For several reasons, Plaintiffs would not be prejudiced by rescheduling Mr. Chen's deposition to the week of June 21 or after. First, as Judge Kugler has previously stated, a trial is not scheduled to occur in this matter until well-beyond 2021. *See* Hrg. Tr. 11-24-20 at 33:9-12 ("I have over 800 pending civil cases, and frankly, I'm informing civil litigants that I will not be reaching their trials *this year, next year, or probably not the year after.*") (emphasis added). Second, from June 1 to October 1, the parties will still be in the midst of taking depositions, as the depositions of bellwether plaintiffs, class representatives, and third-party payors are scheduled to be completed during that period. [ECF 863](#). In fact, through their recent motion for leave to amend their complaints, Plaintiffs propose the addition of 26 putative economic loss class representatives and 6 putative medical monitoring class representatives, who all will be deposed at some yet-to-be-scheduled time. [ECF 1148](#). Third, given his high-level role, Mr. Chen is not designated to cover any of Plaintiffs' 30(b)(6) topics. As the record already reflects, Mr. Chen is not involved in the technical issues relating to the valsartan manufacturing process at issue in this action. *See* Gu, Eric Ph.D. 04/05/2021, 115:15-24 (testifying that Mr. Chen was not involved in "the technical part" of risk assessments); *see also* Tsai, Wen Chien E. 04/08/2021, 96:17-24, 97:1-5 (testifying that Mr. Chen "rarely came to our place" and gave "just some high-level guiding principles" on



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project selection). In fact, unlike those witnesses who were designated on topics relating to testing and quality, Plaintiffs did not request Mr. Chen's deposition be prioritized so that it could be completed ahead of their expert reports on general causation. *See* Hrg. Tr. 12-22-20 at 35:6-25, 36:1-17. In contrast to the lack of any harm to Plaintiffs resulting from rescheduling Mr. Chen's deposition by a few weeks, there is a presumptive burden on the ZHP Parties of having its President deposed. *United States ex rel. Galmines*, 2015 WL 4973626, at *2. Thus, the ZHP Parties should be afforded the opportunity to move to preclude Mr. Chen's deposition based on a sufficient record of testimony, which includes the depositions of Ms. Lin, Mr. Wang, and Mr. Du, among the many other ZHP Party witnesses who have already been deposed.

B. Plaintiffs Should be Required to File a Motion to Compel Mr. Chen's Custodial File, as Ordered by Judge Schneider.

On December 18, 2019, after hearing argument about Mr. Chen's role at ZHP, Judge Schneider denied Plaintiffs' request for Mr. Chen's custodial file, stating: "The Court just does not believe at this time, based on the present record, that a search of Mr. Chen's custodial files will add any material evidence or documents that are not otherwise going to be proven in the case." *See* Hrg. Tr. 12-18-19 at 7:8-9:10, 23:16-19; *see also* Hrg. Tr. 12-18-19 at 24:16-19 ("But in terms of a custodian search for documents, the Court sustains Mr. Goldberg's objections and will remove Mr. Chen from the list, and will approve the list absent his name.").¹ In December 2020, Plaintiffs requested Mr. Chen's deposition, but did not renew their request for Mr. Chen's custodial

¹ At the December 18, 2019 hearing, the ZHP Parties also informed Plaintiffs that Mr. Chen is an official in the Chinese government, and, as such, his custodial file will contain numerous government communications, which would be subject to Chinese state secrecy laws. *See* Hrg. Tr. 12-18-19 at 8:4-7.



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file. However, in directing the ZHP Parties to provide a tentative date for Mr. Chen's deposition, Judge Schneider ordered that "Plaintiffs are also granted leave to file a motion requesting production of Mr. Chen's custodial file." [EFC. 704](#).

On April 23, 2021, the parties met and conferred at the ZHP Parties' request to discuss rescheduling Mr. Chen's deposition to allow for the completion of the depositions scheduled in May 2020 so the ZHP Parties could account for that testimony in moving to preclude Mr. Chen's deposition. Notwithstanding discussing the merits of their request for his deposition, Plaintiffs said nothing about Mr. Chen's custodial file during the meet and confer. Later that day, Plaintiffs sent an email to the ZHP Parties refusing to reschedule Mr. Chen's deposition, and requesting the ZHP Parties agree to produce Mr. Chen's custodial file within 10 days. *See Exhibit B* ("Please advise as to whether you will agree to production of Baohua Chen's custodial file within 10 days. Plaintiffs believe this is a reasonable request, including based on testimony provided by Min Li this past week. If not, we can add to the agenda for this week's conference."). Plaintiffs' informal request, which was not supported with any specific facts contradicting Judge Schneider's earlier ruling regarding Mr. Chen's custodial file, is inconsistent with Judge Schneider's order requiring Plaintiffs to file a motion requesting the production of Mr. Chen's custodial file.

Briefing on such a motion is necessary in light of the particularly sensitive nature of the request for Mr. Chen's custodial file. Given that he is the highest-ranking official at ZHP, which is traded publicly on the Shanghai Stock Exchange, Mr. Chen is provided with business sensitive information that goes far beyond the scope of valsartan, which is just one of more than three dozen APIs ZHP manufactures, as well as information about the dozens of ZHP-affiliated businesses in operation. Moreover, as a legislator in the current National People's Congress ("NPC") as well as



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a member of the Chinese People's Political Consultative Conference ("CPPCC")², Mr. Chen's custodial file is likely to contain numerous documents that would be subject to China's state secrecy laws, and thus would require a thorough review by Chinese counsel prior to production.

C. Over The Weekend Document Requests.

On Saturday evening this past weekend, April 24, 2021, Plaintiffs sent the ZHP Parties a letter with fifteen separate requests for documents and other information on the basis that documents they have recently reviewed, but which have been in Plaintiffs' possession for *over five months*, revealed deficiencies in the ZHP Parties' document productions. See **Exhibit C**.

Plaintiffs short-circuited the meet and confer process by demanding a meet and confer less than one business day after sending their letter, leaving no time for the ZHP Parties to review and evaluate the feasibility of Plaintiffs' requests.³ Plaintiffs then threatened, "if you are unable to meet and confer on Monday regarding this matter, Plaintiffs intend to place this issue on the agenda for the Court's April 28, 2021 discovery conference." See **Exhibit C**.

Plaintiffs cannot create a supposed emergency with documents that the ZHP Parties produced in November 2020 (at the latest), and then deny the ZHP Parties a meaningful opportunity to review the requests, respond, and attempt to resolve these issues amicably through

² In addition to being a Deputy to the 13th National People's Congress and a Standing Member of the 5th Taizhou Municipal Committee of the Chinese People's Political Consultative Conference, Mr. Chen is also Vice President of Zhejiang Chamber of Commerce, Standing Director of Zhejiang Pharmaceutical Association, Chairman of Taizhou Federation of Industry and Commerce, a Member of the Standing Committee of the 16th People's Congress of Linhai City, and a Member of the Fourth Council of Linhai Charity Federation.

³ The ability of the ZHP Parties' counsel to review the issues raised in Plaintiffs' letter in the unrealistic time period requested by Plaintiffs is particularly difficult this week and next due to the celebration of the Chinese national holiday of May Day, which concludes on May 5.



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the meet and confer process. Notably, the ZHP Parties and Plaintiffs have worked in good faith to amicably resolve discovery disputes previously in this matter, and the ZHP Parties will continue to do so in good faith. To that end, the ZHP Parties are investigating Plaintiffs' request and have offered dates to meet and confer with Plaintiffs on Thursday and Friday of this week.

In short, any issue raised in Plaintiffs' Saturday evening letter is not ripe to be heard by the Court during Wednesday's conference. The ZHP Parties have neither acceded to nor rejected Plaintiffs' requests, and the parties have not had an opportunity to meet and confer on Plaintiffs' requests—accordingly, there is no “dispute” to be heard at this time.

6. Briefing Schedule on Motion to Amend

On Monday, April 12, Plaintiffs filed their Motion for Leave to Amend the Valsartan Master Personal Injury, Medical Monitoring, and Economic Loss Complaints (the “Motion”). Prior to Plaintiffs' filing, on April 1, defense counsel emailed the PEC requesting to meet and confer regarding Plaintiffs' then-anticipated motion, including to discuss the scope of Plaintiffs' anticipated amendments, and to confer on the timing and length of Defendants' response. Defendants renewed their request on April 8 and, following an email exchange with a representative of the PEC, proposed that the briefing schedule be modified to extend the timing of Defendants' anticipated opposition and Plaintiffs' anticipated reply, given the number of parties with an interest in the motion, and the number of issues Defendants anticipated would be raised by Plaintiffs' proposed amendments. Citing timing concerns and the fact that Plaintiffs' filing was imminent, on April 10, Plaintiffs' proposed that the parties table their discussions until after Plaintiffs' Motion had been filed.



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After Plaintiffs filed their motion, the parties met and conferred to discuss an extension of the briefing schedule to afford Defendants additional time to oppose Plaintiffs' proposed amendments, and to afford Plaintiffs additional time to reply to Defendants' opposition.

In furtherance of these negotiations, the parties generally discussed that (1) any extension afforded Defendants in opposing Plaintiffs' motion should be reciprocal, such that Plaintiffs received an equal amount of time to reply to Defendants' opposition; and (2) that any additional pages afforded Defendants in their briefing also be reciprocal, such that Plaintiffs received the same number of additional pages to reply to Defendants' opposition briefs. After exchanging several emails regarding the schedule, on April 24, the parties conferred. Defendants proposed the following schedule:

- Deadline for the Manufacturing Defendants', Wholesaler Defendants', and Pharmacy Defendants' respective oppositions to Plaintiffs' motion: May 27, 2021
- Deadline for Plaintiffs' reply brief: July 12, 2021
- Deadline for Defendants' respective surreplies: August 2, 2021

Defendants also proposed a very modest increase of 10 pages (*i.e.* 50 pages) to the total number of pages afforded the Pharmacy Defendants in their opposition to Plaintiffs' motion, and advised that neither the Manufacturers nor the Wholesalers sought any additional pages for their opposition briefs.

On April 27, shortly before the filing of this letter, Plaintiffs' counsel advised that Plaintiffs do not agree to any of Defendants' proposals. Plaintiffs instead proposed that both sides be afforded 60 days to brief their respective opposition and reply briefs, such that Defendants' respective oppositions would be due June 11, 2021, and Plaintiffs' reply would be due August 10,



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2021. In other words, Plaintiffs do not object to the extension of all briefing deadlines on their motion. Instead, they submit that the briefing deadlines should be extended out further than the dates proposed by Defendants. Plaintiffs also advised that they oppose Defendants' proposal to request leave to file surreplies, and oppose the Pharmacy Defendants' request for an additional 10 pages to brief the numerous issues raised by Plaintiffs' motion.

In view of Plaintiffs' position on these issues, Defendants respectfully request that the Court enter Defendants' original proposal, and grant the following requests for relief:

- (1) Extended briefing deadlines for Defendants' opposition to Plaintiffs' motion and Plaintiffs' reply, pursuant to the schedule set forth above. (Plaintiffs do not object to extensions, but submit that the briefing deadlines should be extended out further than the dates proposed by Defendants.)
- (2) Permission for each tier of Defendants to file a surreply brief, to be filed no later than August 2, 2021.
- (3) Permission for the Pharmacy Defendants to utilize an additional 10 pages of briefing in opposing Plaintiffs' motion.

Defendants will be prepared to discuss this proposal, and the basis for their requested relief, at tomorrow's case management conference.

7. PFS Deficiency Show Cause Process

A. Cases Addressed at the March 31, 2021 Case Management Conference:

Defendants note that the Court orally issued an order to show cause returnable at the April 28, 2021 Case Management Conference in one matter:



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- Williams, Naomi v. Aurobindo Pharma, Ltd., et al – 20-cv-8772

However, the case was previously dismissed with prejudice on January 27, 2021, and therefore the Clerk of the Court did not issue an order to show cause. As such, the issue is resolved and there are no dismissals pending at this conference.

B. Second Listing Cases – Order to Show Cause Requested:

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these three cases were previously listed on the agenda for a prior CMC. Defendants attempted to schedule a meet and confer with Plaintiffs' Leadership Counsel on April 13, 14, and 20th but received no response. Defendants then reached out to individual counsel for each case which would have been subject to a second listing at this Case Management Conference. Defendants resolved a number of disputes in matters which have been removed from this agenda, but following these individual meet and confers outstanding deficiencies remain in the three (3) cases identified below. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next Case Management Conference, as to why the case should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the April 28, 2021 Case Management Conference:



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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Notice Sent
1.	Mundy, Gwendolyn v. Doe	20-cv-08285	Watts Guerra, LLP	III. G. C Failure to itemize or provide amount of medical expense(s).	2/26/21
2.	Ragland, Arnold v. Zhejiang Huahai Pharmaceutical, Co., Ltd., et al.	20-cv-04363	Watts Guerra, LLP	I.E - Failed to respond. Section E – Representative information. II.C-K - Failed to respond. Sections II.C, D, G to J. III.F - Failed to respond. Section III.F IV.E - Failed to respond. - Witnesses XI.A.1, 6 - Failed to provide undated, completed and signed authorizations. XII - Failed attach completed, dated and signed declarations.	7/6/20
3.	Canfara, Michael- Est. of (Mashrique, P.) v. Rite Aid Corp.	20-cv-10857	Stark & Stark	No authorizations. PFS substantially incomplete.	2/9/21



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C. First Listing Cases – Remaining Core Deficiencies:

The following Plaintiff Fact Sheets contains core deficiencies which remain unresolved. Defendants attempted to schedule a meet and confer with Plaintiff Leadership Counsel on April 13, 14, and 20th but received no response. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to attempt to meet and confer to resolve these deficiencies before the next Case Management Conference.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	PFS Due Date
1.	Kopp, Daniel v. Aurobindo Pharma, Ltd., et al.	20-cv-15327	Levin Papantonio	Need billing records	3/19/21
2.	Rex, Karen v. Zhejiang Huahai Pharmaceutical, Co., Ltd., et al.	20-cv-15321	Levin Papantonio	Need billing records	3/19/21
3.	Nelson, Vanessa – (E.O. Marian Nelson) v. Aurobindo Pharma, Ltd., et al.	20-cv-16124	Hollis Law Firm, P.A.	No Amended PFS Filed. I.C.1 – Plaintiff stated that there is a Valsartan container or packaging in her possession in section III.B.5 of the PFS. One photograph of a Valsartan container was produced. However, the produced photograph is blurry and does not visibly display the NDC code. Please produce clear photographs of the Valsartan container in Plaintiff's possession that visibly display	3/15/21



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the NDC code and all sides of the referenced container.

I.E.4 – Plaintiff failed to respond to the request to identify the court and the corresponding case number of where the answering Plaintiff was appointed as a representative for the decedent Plaintiff. Also, no documentation has been produced from a court showing the appointment of Vanessa Nelson as a representative for the decedent.

III.F.3.a – Plaintiff’s answer “N/A” is an insufficient response to the requests to identify her annual gross income for every year following the injury or condition she claims was resulted from Valsartan use, as Plaintiff stated her cancer that she claims resulted from Valsartan use was diagnosed on 12/17/2018 and Plaintiff indicates in section II of the PFS that Plaintiff was employed through 2020. However, Plaintiff has only provided her gross annual income through 2018. Please state Plaintiff’s annual gross income for the years 2019 and 2020 and produce the corresponding W-2’s for said years in relation to the alleged wage loss claim.

III.F.4 – Plaintiff failed to provide any substantive response to the request to



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identify the total amount of income she claims that she lost as a result of any condition caused by Valsartan use.

III.G.a – Plaintiff produced billing records that correspond to some of the identified claimed medical expenses. However, Plaintiff also produced billing records from Tennessee Oncology and additional Saint Thomas Rutherford Hospital medical expenses that are not identified in the PFS and, as a result, it is unclear if Plaintiff is intending to assert said additional medical expenses in connection with the instant lawsuit or not.

IV.B.3 – Plaintiff did not provide the complete end date for her treatment with Murfreesboro Radiology.

V.E.2 & V.E.3 – Plaintiff stated that she has not consumed alcohol in the past ten years in the PFS. However, the produced medical records from 2019 indicate that Plaintiff drinks alcohol socially.

V.F.7 – Plaintiff identified a depression diagnosis in section III.3, however the depression diagnosis is not identified by Plaintiff in this section. Please also provide the name, address, and phone number for the health care provider, the approximate date of onset, and treatment received and



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				<p>outcome in relation to the aforesaid diagnosis.</p> <p>V.G.1 – V.G.4 – Please provide the name, address, and phone number for the health care provider, the approximate date of onset, and treatment received and outcome in relation to the depression diagnosis identified in section III.E.</p> <p>VI.A.4 – Plaintiff did not state the frequency of use for the identified medication Hydrochlorothiazide.</p> <p>X.A.1.a – No death certificate or letters of administration were produced.</p> <p>XI.A.1 – No health care authorizations were produced for the following health care providers: Tennessee Oncology; Tri-Star Medical Group Gastroenterology Specialists of TN; Steven Thomas, MD; Richard Michaelson, Jr., MD; The Surgical Clinic; William H. Polk, Jr., MD; Hao Ho, MD; Kaori Saito, MD, or Paul Menke, MD. Also, the produced health care authorizations are dated. Please produce properly executed and undated health care authorizations for all identified health care providers, treatment facilities, and pharmacies, including the above-stated health care providers.</p> <p>XI.A.2 – Plaintiff has asserted an alleged wage loss claim,</p>	
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				<p>however no tax return authorizations were produced. Please produce properly executed tax return authorizations.</p> <p>XI.A.3 – Plaintiff has asserted an alleged wage loss claim, however no employment records authorizations were produced. Please produce properly executed and undated employment records authorizations for each respective employer.</p> <p>XI.A.5 – Plaintiff identified a Social Security Disability claim in the PFS. However, no disability records authorizations were produced. Please produce properly executed and undated disability records authorizations.</p> <p>XI.A.6 – No insurance records authorization were produced. Please produce properly executed and undated insurance records authorizations for each identified insurance carrier.</p> <p>XI.B.9 – One photograph of a Valsartan container was produced. However, the produced photograph is blurry and does not visibly display the NDC code. Please produce clear photographs of the Valsartan container in Plaintiff's possession that visibly display the NDC code and all sides of the referenced container.</p>	
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				<p>XI.B.17 – Plaintiff indicated that she worked in the years 2019 and 2020, however no W-2's were produced for 2019 and 2020. Also, the document demand in the PFS requests the production of federal tax returns for each of the five (5) years preceding the injury alleged to be caused by Valsartan use, but no tax returns were produced.</p> <p>XI.B.18 – No billing records were produced that correspond to the following identified claimed medical expenses: the 12/17/2018 expense from Stonecrest Medical Center; the 1/23/2019 expense from Path Group; or the 4/6/2019 expense from Murfreesboro Radiology.</p> <p>XI.B.21 – The decedent's Last Will and Testament was produced. However, no death certificate or letters of administration were produced.</p>	
4.	Hockenjos, Virginia – (E.O. Alan Hockenjos) v. Hetero Drugs, Ltd., et al.	20-cv-20477	Hollis Law Firm, P.A.	<p>I.C.1, XI.B.9 & XI.B.10 – Plaintiff stated that there is a Valsartan packaging or container in her possession in section III.B.5 of the PFS. Plaintiff produced additional photographs of Valsartan containers with the Amended PFS. However, the additional produced photographs do not visibly display the NDC code(s). Please produce additional photographs of the Valsartan containers in Plaintiff's possession that visibly display the NDC</p>	3/24/21



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				code(s) and all sides of the referenced containers in Plaintiff's possession. XI.B.18 – Plaintiff did not produce any billing records that correspond to the identified medical expense from Lehigh Valley Health.	
5.	Wilcox, John v. Mylan Laboratories Ltd., et al	20-cv-17939	Babin Law	No authorizations, medical records, proof of purchase. Extensive incomplete PFS sections see deficiency letter.	3/23/21
6.	Darris Knox, Individually and as a Representative of Andrae Knox v. CVS Health	20-cv-16419	Watts Guerra, LLP	No response to deficiency notice	1/29/21
7.	Randall Harrah v. Zhejiang Huahai Pharmaceutical Co., Ltd.	21-cv-00246	Hollis Law Firm	No response to deficiency notice	3/31/21
8.	James E. Gibson Jr, et al. v. Zhejiang Huahai Pharmaceutical Co., Ltd.	1:20-cv-12117	Douglas & London	XI.A.1 - Failed to provide properly signed, undated, and completed authorization in the form authorized by the Court. XI.A.6 - Failed to provide properly signed, undated, and completed authorization.	12/28/20
9.	Robinette Lawler v. Zhejiang Huahai Pharmaceuticals Co., Ltd.	20-cv-19687	Davis & Crump	XI. A. 1 Failure to provide Health Care Authorizations for Dr. Noel Duplantier.	3/2/21
10.	Becton, Norman v. Aurobindo Pharma, Ltd. et al.	20-cv-13752	Hollis Law Firm, P.A.	No PFS Filed.	PFS Due - 11/30/21



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11.	Sundermeier, Julie v. Aurobindo Pharma, Ltd., et al.	21-cv-01075	Levin Papantonio	No PFS Filed.	PFS Due - 3/24/21
12.	Aloian, Debbie, Individually and as Representative of Richard Aloian, Deceased v. Hetero Drugs, Ltd., et al.	21-cv-02119	Watts Guerra, LLP	No PFS Filed.	PFS Due - 4/9/21
13.	DeClerk, Thomas, et al. v. Hetero Drugs, Ltd., et al.	21-cv-01016	Brent Coon & Assoc.	No PFS Filed.	PFS Due - 3/23/21

Respectfully submitted,

/s/ Lori G. Cohen

Lori G. Cohen

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